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U.S. Pharmaceuticals Division

March 22, 1999 99 MAR 24 P1:36

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Sir:

We wish to thank the agency for this opportunity to offer our comments on the draft Guidance for Industry; **Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Containing Certain Active Moieties/Active Ingredients Based on a Biopharmaceutics Classification System (Docket No. 99D-0121)**. We hope that our comments will help improve this document and make it more widely useful.

We salute the agency's effort to reduce the regulatory burden on the Pharmaceutical Industry, and the exposure of subjects to pharmaceuticals when justified by good science.

Our only recommendation is to broaden the scope of this guidance ever so slightly to include Immediate Release Oral Suspension Dosage Forms. While a suspension product for many of these drugs may not currently be expected, the concepts being developed in the guidance should be applicable to such products. We suggest that the document state that if all the same criteria are met with an immediate release oral suspension product, the guidance would apply to it as well.

Respectfully submitted,

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99D-0121

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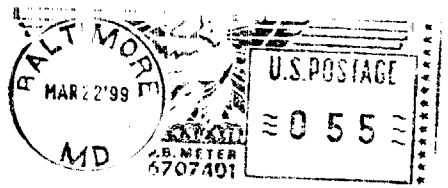

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